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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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MEMORANDUM

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SUBJECT: Rodenticides Tier II: Review of Human Incidents

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I. ACTION REQUESTED

As part of the Rodenticide Risk Mitigation Decision (RMD), and the subsequent Notice of Intent to Cancel (NOIC), the Environmental Protection Agency's Office of Pesticide Programs' Pesticide Re-evaluation Division requested an analysis of human incidents involving exposure to rodenticides.

When looking across human incident data sources, as well as the open literature, rodenticides are found to be involved in numerous incidents, including incidents involving children less than 6 years old. Almost all incidents occurring due to rodenticide exposure are the result of label directions to keep bait away from children, pets and non-target wildlife not being followed. While the resulting human exposures to rodenticides have the potential to result in severe outcomes and/or medical care, exposures generally result in no clinical harm to children. Also, similar to trends identified in previous reviews, analysis of AAPCC data showed the ratio of

incidents to children under six years of age to total incidents per pesticide classifications is highest for rodenticides than the other pesticide classifications.

II. BACKGROUND

In the U.S., rodenticides are registered for use by the Environmental Protection Agency's (EPA or Agency) Office of Pesticide Programs (OPP or Office) for use against pest rodents (e.g., rats, mice, gophers, etc.) associated with a variety of use sites (e.g., agricultural fields, restaurants, homes, etc.). Rodenticides have been most recently reviewed under OPP's Reregistration program in the 1990s. As a result of these reviews, rodenticide agricultural field uses and residential tracking powder products were successfully mitigated via classification as restricted use pesticides (RUP; the one exception was manual underground baiting products for use in agricultural fields, which did not necessitate an RUP classification). Additionally, rodenticides employed to preserve native plant and animal species on islands were determined to be appropriately managed by the U.S. Fish and Wildlife Service, rendering mitigation unnecessary. However, the path forward to mitigate risk from the remaining rodenticide use pattern (rodenticides formulated as baits/pellets used against commensal rodents[1] in residential-type settings) met with some resistance, resulting in the Rodenticide Stakeholder Workgroup (RSW), a subcommittee under the federally-chartered advisory body, the Pesticide Program Dialogue Committee (PPDC). The RSW issued recommendations, and helped inform the Agency's 2008 Risk Mitigation Decision for Ten Rodenticides (RMD). Under the terms of the 2008 RMD, products marketed to the general non-professional user or homeowner must be modified to adopt a variety of mitigation measure to continue to meet the FIFRA standard. These risk mitigation measures included requiring rodenticide products used in homes and marketed to general residential consumers be sold only with bait stations. Additionally, the RMD required the second-generation anticoagulant class of rodenticides to be sold in a way to limit sale to general residential consumers. The RMD provided registrants until June 4, 2011 to comply with the mitigation measures. However, as of June 4, 2011 not all rodenticide products complied. As a consequence, the Agency is preparing to commence cancellation proceedings under FIFRA section 6(b).

Since the 1960s, the Unites States Department of Agriculture (USDA, which regulated pesticides until the formation of the EPA) and then the EPA, have worked to regulate these rodenticides by mandating they be housed in bait-stations that prevent exposure to non-target organisms. The primary reason driving this effort was the number of accidental (unintentional) exposures involving these products. Subsequently, at this juncture, the Agency is compiling information to support the upcoming NOIC, and this memo in particular focuses on residential rodenticide use and their impact on humans.

Currently, there are 10 active ingredients and two sodium salts that are formulated as baits and used in residential-type settings, as well as hold active registrations. Furthermore, they can be

[1] Commensal rodents are rodents that live in close association with humans and depend upon them for shelter and/or for some of their sustenance. In the continental U.S., the term commensal rodents includes Norway rats (*Rattus norvegicus*), roof rats (*Rattus rattus*), and house mice (*Mus musculus*).

grouped according to three main categories: first-generation anticoagulants, second-generation anticoagulants and non-anticoagulants. They are classified as follows:

- First-generation anticoagulant
  - chlorophacinone (PC code 067707)
  - diphacinone (PC code 067701)
  - diphacinone sodium salt (PC code 067705)
  - warfarin (PC code 086002)
  - warfarin sodium salt (PC code 086003)

- Second-generation anticoagulant
  - brodifacoum (PC code 112701)
  - bromadiolone (PC code 112001)
  - difenacoum (PC code 119901)
  - difethalione (PC code 128967)

- Non-anticoagulant
  - bromethalin (PC code 112802)
  - cholecalciferol (PC code 202901)
  - zinc phosphide (PC code 088601)

Rodenticides are designed to kill mammals, so their effects on humans and non-target mammals are qualitatively the same as their effects on target pests, unlike other pesticides such as herbicides and certain insecticides where adverse effects on mammals tend to be different in nature than their effects on target pests. Rodenticides can be divided into three broad classes in terms of their effects: first generation anticoagulants, second generation anti-coagulants, and non-anticoagulants. The first- and second generation anti-coagulants interfere with blood clotting and death results from hemorrhage. For both first generation and second generation anticoagulants, primary manifestations include nosebleeds, bleeding gums, hematuria, melena, and extensive ecchymoses (bruises). Patients may also have symptoms of anemia, including fatigue and dyspnea on exertion. If the poisoning is severe, the patient may progress to shock and death. The first generation anti-coagulants generally require multiple doses to deliver a lethal dose while the second generation anticoagulants can deliver a lethal dose to rodents in one night's feeding. The non-anticoagulant rodenticides work in different ways to cause death.

Each of these is discussed below:

- first generation anti-coagulants disrupt the production in the liver of vitamin K dependent blood-clotting factors II (prothrombin), VII, IX, and X. Due to the long half-lives of the vitamin K-dependent clotting factors, the anticoagulant effect doesn't occur in the rodent until after several days of ingestion The onset of lengthened prothrombin time (PT) from a toxic dose may occur within 24 hours, and reach a maximum in 36-72 hours at a dose much lower than the dose that can cause hemorrhage (Reigart J.R. et.al, 1999). The agents also increase permeability of capillaries throughout the body, leading to widespread internal hemorrhage. It is noted that chlorophacinone, diphacinone, and diphacinone sodium salt block different binding sites than those blocked by warfarin and warfarin sodium salt.

- second generation anticoagulants are more acutely toxic than first generation agents and can cause lethal effects to rodents in a single dose. Like the first generation anticoagulants these agents block the formation of the active form of vitamin K, which in turn inhibits the production of coagulation factors in the liver. These chemicals block the same binding site that warfarin and warfarin sodium block; however, second generation anticoagulants have much longer half-lives in the body (Batten and Bratt, 1990). Similar to the first generation anticoagulants, the toxic effects of these agents usually begin several days after ingestion, because of the long half-life of the coagulation factors.

The non-anticoagulants work in a variety of ways and no single common mechanism exists. For example:

- Bromethalin, causes decreased production of ATP in the cells of the central nervous system by uncoupling oxidative phosphorylation in the mitochondria. Low levels of ATP reduce the efficiency of the enzyme Na/K ATPase, leading to increased intracellular sodium levels. This in turn draws more water into neuronal cells (cerebral edema) and increases intracranial pressure which can be lethal. Symptoms and signs of cerebral edema include headache, dizziness, nausea, numbness, weakness, loss of coordination or balance, altered level of consciousness, respiratory depression, seizures, and death.
- Cholecalciferol increases calcium absorption from food, and mobilizes calcium from bone which leads to hypercalcemia (increased calcium levels in blood). Hypercalcemia can cause formation of calcium crystals in internal organs such as blood vessels, kidneys, stomach wall and lungs (Chavhan S.G.et.al, 2011). Abnormal heart conduction and irregular heartbeats can also occur since the heart tissue is sensitive to changes in blood calcium levels. Symptoms and signs of cholecalciferol poisoning may include fatigue, weakness, nausea, anorexia, headache and irregular heartbeats (Goldfrank et.al, 2010). Acute renal tubular injury due to hypercalcemia may cause excessive urination, increased water intake, protein in urine and increased blood urea levels. Prolonged hypercalcemia may eventually cause kidney failure due to formation of kidney stones and calcium deposition in kidney tissues.
- Zinc phosphide can quickly produce toxic phosphine gas when it comes in contact with acids or water. Phosphine is thought to produce toxicity by blocking cytochrome oxidase and, inhibiting oxidative phosphorylation which may lead to cell death (Perry H.E., 1998). Most of the tissue damage can occur in liver, kidneys and heart. Patients may present with symptoms such as, severe gastrointestinal irritation, nausea, vomiting (with fishy odor), chills, tightness of chest, difficulty in breathing and cough (from pulmonary edema). Development of the liver failure can cause jaundice and excessive hemorrhage. Delirium, convulsions and coma may result from renal tubular damage. Common cause of death is from ventricular arrhythmias and shock due to myocardial damage (Reigart J.R., 1999).

HED previously reviewed Poison Control Center (PCC) data for residential exposure to rodenticides found that anticoagulant rodenticides are responsible for a large number of exposures (over 12,000 per year, 1993-96) in children under six years old, accounting for 20% of

all pesticide exposures. Fortunately, the majority of these exposures, 97%, do not result in significant symptoms base on those cases which received follow up to determine medical outcome. Compared to other types of pesticides, anticoagulants (including 1st and 2nd generation) were the least likely to have symptomatic outcomes, accounting for only 2.65% of the total symptomatic cases due to all pesticides. Despite the relatively low number of symptomatic cases, anticoagulants are much more likely to receive medical treatment accounting for 41% of all pesticide-related cases seen in a health care facility and 15% of all hospitalized cases (Blondell 03/22/1999). A follow-up analysis analyzed incident reports primarily concerning children (Blondell and Spann, 06/03/1999, D256673). They addressed under-reporting, finding that a number of surveys indicate that under-reporting of poisoning events to the AAPCC is significant; based on these studies, HED estimates that only a quarter of the total number of pesticide poisoning incidents are reported to the AAPCC or state counterparts. In 2006, an updated review of rodenticides primarily concerning children (Hawkins and Allender, 01/09/2006, D332563) and an addendum (Winfield, 05/08/2008, D332561) made the following summary findings:

- The combination of 9-rodenticides (difenacoum was not included in this analysis) is below the composite of all pesticides in the production of symptoms, in the production of moderate symptoms and in the production of major symptoms.
- The ratio of children seen in a Health Care Facility as a result of a potential exposure to the 9-rodenticides group is almost 26% higher than the composite of all pesticides.
- No apparent annual trend is noticed in the 5 year-span for the 9-rodenticides group.
- Brodifacoum contributes almost 80% of the total exposure cases of the group; this may be due to market share.

III. DISCUSSION AND ANALYSIS

The Agency generally relies on toxicity studies conducted on animals and exposure information relevant to the pesticide's use pattern when registering a pesticide. After a pesticide is registered; however, human observational data about the effects and exposure of registered pesticides may be collected and analyzed. For this memorandum and review, human observational data, or incidents, from the following sources were analyzed:

- summary data from the American Association of Poison Control Centers (AAPCC)
- human incident (poisoning) data from OPP's Incident Data System (IDS) database,
- NIOSH Sentinel Event Notification System for Occupational Risks (SENSOR),
- the Agency-sponsored National Pesticide Information Center (NPIC),
- California's Pesticide Incident Surveillance Program (PISP), and
- open literature.

Specifically, this review considers these different sources of human observational information at the request of the Environmental Protection Agency's Office of Pesticide Programs' Pesticide Re-evaluation Division in anticipation of one or more Notices of Intent to Cancel (NOIC).

A. Human Incident Data

Incident information can provide important feedback to the Agency, assisting in determining actual real-world exposures and risks posed by pesticides/pesticide products. Incident data are collected systematically, but differently, across the different databases used by the Agency with respect to such issues as coverage, certainty/confidence, fields/parameters reported, and usability. The aforementioned five pesticide incident data sources (IDS, NIOSH/SENSOR, NPIC, California PISP, and AAPCC) were used in this report since they provide useful content and historical perspective. Various other comparable sources of data are available (e.g. the Bureau of Labor Statistics, emergency room outpatient surveillance, etc.) but are believed to be of limited additional utility and were not investigated. By looking across the five data sources which were used, the Agency is confident that we are able to consider adequate and appropriate information to discern trends and patterns in incident poisonings associated with the following rodenticides used for commensal rodent control in bait form: brodifacoum (PC Code 112701), bromadiolone (PC Code 112001), bromethalin (PC Code 112802), chlorophacinone (PC Code 067707), cholecalciferol (PC Code 802901), difenacoum (PC Code 119901), difethialone (PC Code 128967), diphacinone (PC Code067701), diphacinone sodium salt (PC Code 067705), warfarin (PC Code086002), warfarin sodium salt (PC Code 086003), and zinc phosphide (PC Code 088601).

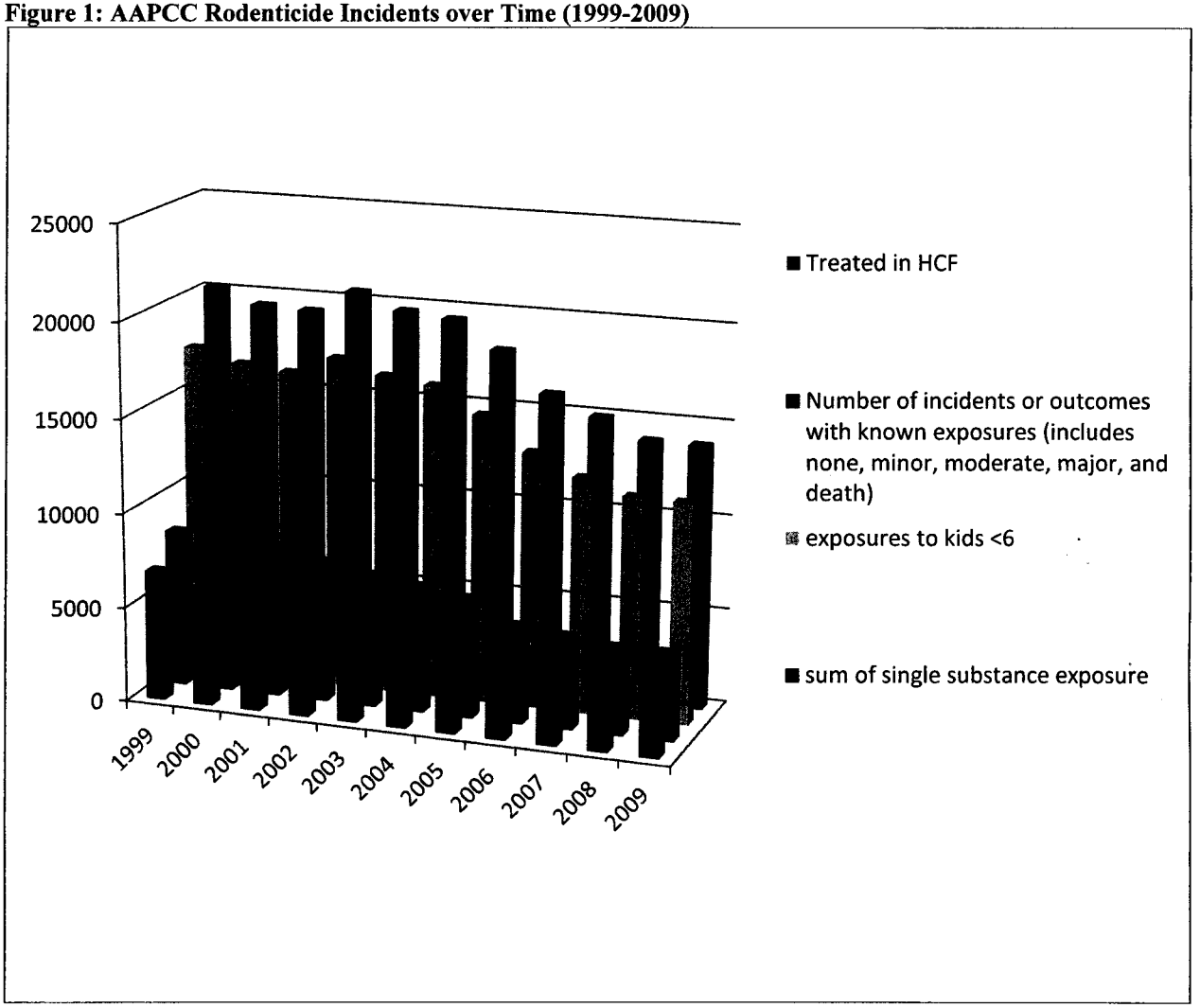
1. American Association of Poison Control Centers (AAPCC)

The American Association of Poison Control Centers (AAPCC) is a non-profit, national organization founded in 1958 that represents the poison control centers of the United States and the interests of poison prevention and treatment of poisoning. All of the calls to a poison control center are managed by a medical professional trained to answer questions about poisons. Additionally, AAPCC reports provide clearly summarized information on pesticide incidents within the context of other poisoning events.
http://www.aapcc.org/dnn/NPDSPoisonData/NPDSAnnualReports.aspx

AAPCC produces an annual summary report giving statistics and information on all the poisonings reported to PCCs in a calendar year. The AAPCC annual summary data break down the incident data in terms of rodenticides[2]. The Agency examined the rodenticide data from 1999 to 2009, and found that an average of 17,000 exposures were reported each year and approximately 5000 of these were treated in a health care facility each year. Approximately 85% (~15,000 per year) of these 17,000 exposures occurred to children under 6 years old over the 11 year period analyzed (Figure 1).

[2] Note that in AAPCC rodenticides include the following categories/pesticides: ANTU, bromethalin, cholecalciferol, cyanide, long-acting anticoagulant (2nd generation anticoagulants), other, PNU, sodium monofluroacetate, strychnine, unknown, warfarin-type anticoagulant (1st generation anticoagulants), and zinc phosphide.

Figure 1: AAPCC Rodenticide Incidents over Time (1999-2009)



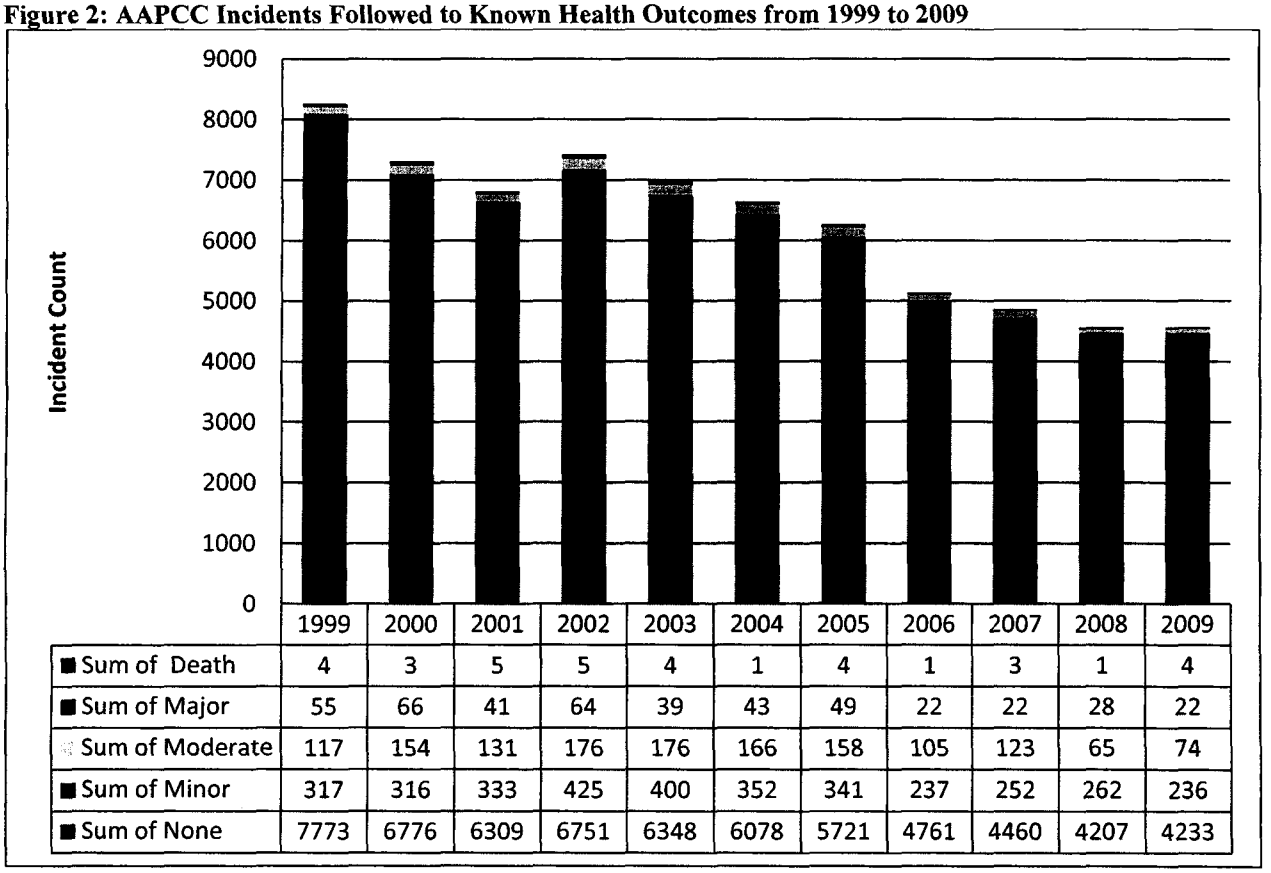
The Agency further examined the AAPCC rodenticide incidents with known exposure outcomes. Known exposures are categorized as follows:

- Death,
- Major - symptoms are life-threatening or result in residual disability or disfigurement (coma, cardiovascular instability, repeated seizures),
- Moderate – symptoms are more pronounced, prolonged, or more of a systemic nature than minor symptoms with no residual disability. Usually some form or treatment is indicated (high fever, disorientation),
- Minor – symptoms are minimal with no residual disability (skin irritation, drowsiness, mild gastrointestinal symptoms), or
- None – patient developed no symptoms as a result of exposure.

Approximately 78,000 of the rodenticide related calls received over the 11 year period had a known outcome. The Agency found that 92% of these calls reported no symptoms as a result of

the rodenticide exposure (figure 2)[3]. Further, when compared to other types of pesticides, rodenticides were the least likely to have symptomatic outcomes, accounting for only 2% of the total symptomatic cases due to all pesticides from 1999-2009.

Figure 2: AAPCC Incidents Followed to Known Health Outcomes from 1999 to 2009



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Sum of Death	4	3	5	5	4	1	4	1	3	1	4
Sum of Major	55	66	41	64	39	43	49	22	22	28	22
Sum of Moderate	117	154	131	176	176	166	158	105	123	65	74
Sum of Minor	317	316	333	425	400	352	341	237	252	262	236
Sum of None	7773	6776	6309	6751	6348	6078	5721	4761	4460	4207	4233

Preponderance of exposure to children

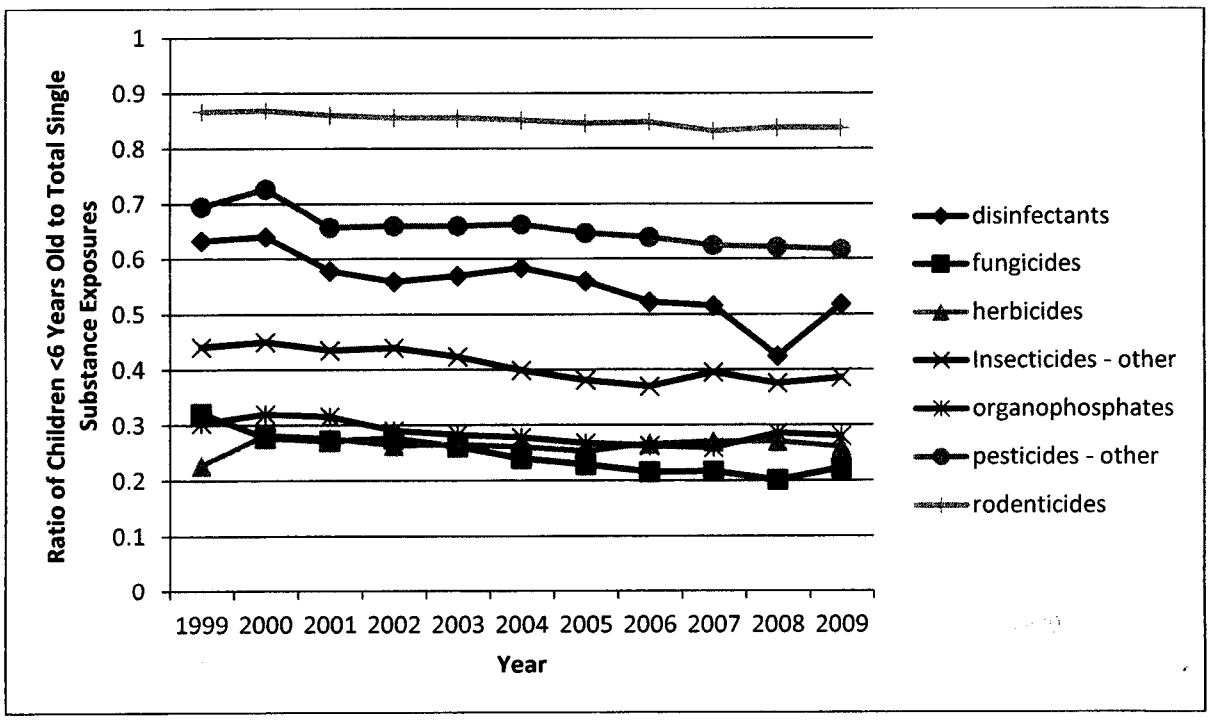
The AAPCC incidents from 1999-2009, were further analyzed with respect to child exposure. The Agency found that insecticides are responsible for more total incidents and incidents to children less than six years of age than other pesticide classes. However, the ratio of incidents to children under six years of age to total incidents per pesticide classifications is highest for rodenticides than the other pesticide classes (Table 1, Figure 3). Approximately 16% of all reported exposures to pesticides are due to rodenticide exposures and 26% of all reported pesticide-related exposures to children under 6 are due to rodenticide exposures. In addition, approximately 25% of all pesticide-related cases seen in a health care facility were related to rodenticide exposures.

[3] These calls include all age groups and are inclusive of attempted suicides and malicious intent cases.

Table 1. Ratio of Exposures to Children <6 years old to Sum of Single Exposures per Pesticide Category in AAPCC from 1999-2009

Pesticide Category	% Exposures to Children	Exposures to Children <6 years old	Total Exposures
disinfectants	55%	122,868	224,578
fungicides	25%	3,593	14,308
herbicides	26%	26,774	101,832
insecticides	41%	192,745	474,149
organophosphates	29%	24,877	84,931
other pesticides	65%	98,309	150,196
rodenticides	85%	166,250	195,263

Figure 3: Ratio of Exposed Children Less Than 6 Years Old to Sum of Single Exposures per Pesticide Category (1999-2009).



More detailed analysis of AAPCC raw data from 1999 to 2005 of the children's exposures, demonstrates that an average of 3686 (or 26%) children less than 6 years old exposed to rodenticides were treated/evaluated and released at a health care facility or admitted to a non-critical care unit per year as a result rodenticide exposure. The analysis also demonstrates that an average of 128 cases per year (or 1%) of the exposures to children result in a medical outcome classified by the AAPCC as minor, moderate or major (Table 2). In addition, of all pesticide-related cases involving children less than 6 years old, approximately 39% of those seen in a health care facility are related to rodenticide exposure and 13% of hospitalization cases are related to rodenticide exposure. Further, no deaths to children are reported.

Table 2: 1999-2005 Pesticide vs. Rodenticide Comparison of Cases to Children <6 Years Old.

Exposure Outcome	Rodenticides (% of Total)	All Pesticides (% of Total)
None	35%	29%
Minor	1%	11%
Moderate	0.1%	1%
Major	0.02%	0.07%
All Symptomatic	1%	12%
Healthcare		
Any Level of Care	26%	14%
Admitted to ICU	0.1%	0.2%

Nevertheless, severe outcomes from human exposures to rodenticides do occur. From 1999-2005, 894 cases were reported having minor, moderate, or major effects. For cases reporting moderate or major effects, the most common effect reported was hematological, 37% and 55% respectively (Table 3). These symptoms are likely a result from anticoagulant rodenticides' abilities to interfere with blood clotting and are likely the result of rodenticide exposure.

Table 3. AAPCC Reported Exposure Symptoms for Symptomatic Children Less Than 6 Exposed to Rodenticide from 1999- 2005

Level of Effect	Total Exposures	Reported Exposure Symptoms*								
		Neurological	*Ocular*	*Renal*	*Respiratory*	*Misc.*	*Cardio*	*Dermal*	*GI*	*Hematological*
Minor effect	727	15 (2%)	17 (2%)	0	20 (3%)	180 (25%)	0	18 (2%)	277 (38%)	36(5%)
Moderate effect	147	7 (5%)	1 (1%)	4 (3%)	2 (1%)	22 (15%)	0	8 (5%)	34 (23%)	55 (37%)
Major effect	20	1 (5%)	0	0	2 (10%)	5 (25%)	0	2 (10%)	4 (20%)	11 (55%)

* The categories are not mutually exclusive (i.e. a person could report both a neurological and renal symptom)

2. OPP Incident Data System (IDS)

The OPP IDS includes reports of alleged human health incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6 (a) (2) reports from registrants and reports from other federal and state health and environmental agencies and individual consumers. Since 1992, OPP has compiled these reports in IDS. IDS contain reports from across the U.S. and most incidents contained in the system have all relevant product information recorded. Case reports or "narratives" are provided for each incident, with varying levels of detail; however, there is no effort at validating or assessing how likely it is that the reported exposure is causally related to the reported outcome. Because IDS has such extensive coverage, it is useful for providing temporal trend information and determining whether risk mitigation has helped reduce potential pesticide exposure and decreased the number of potential incidents reported to IDS.

For this evaluation, the OPP IDS was utilized for pesticide incident data on the following rodenticide active ingredients: brodifacoum (PC Code 112701), bromadiolone (PC Code

112001), bromethalin (PC Code 112802), chlorophacinone (PC Code 067707), cholecalciferol (PC Code 802901), difenacoum (PC Code 119901), difethialone (PC Code 128967), diphacinone (PC Code 067701), diphacinone sodium salt (PC Code 067705), warfarin (PC Code 086002), warfarin sodium salt (PC Code 086003), and zinc phosphide (PC Code 088601). This database search was done to identify the frequency and severity of the health effects as well as potential patterns and trends attributed to exposures from rodenticides formulated as baits used for control of commensal rodents. Reports submitted to the IDS represent anecdotal reports or allegations only, and are not necessarily confirmed, validated, or investigated by medical professionals unless otherwise stated in the report.

IDS consists of two separate modules: Main IDS and Aggregate IDS. Because of the reporting requirements, IDS records incidents resulting in higher severity outcomes in the Main IDS module. However, there are some less severe incidents (i.e., HD and HE) that have been submitted to OPP as reports, and therefore, these are captured in Main IDS.
The higher severity outcomes include:

- H-A (death): If the person died;
- H-B (major): If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability; and
- H-C (moderate): If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms, usually some form of treatment of the person would have been indicated, symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

This system stores incident data for death (HA) and major (HB) and moderate (HC) incidents, and it includes more details about the location, date and nature of the incident. Main IDS incidents involving only one pesticide are considered to provide more certain information about the potential effects of exposure from the pesticide, and therefore these incidents are reviewed individually in this assessment. When an incident involves more than one pesticide, it is difficult to determine which effects are attributed to the pesticide being considered.

IDS records the less severe human incidents that are reported by registrants as counts in the Aggregate IDS module. The less severe human incidents include:

- H-D (minor): If the person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved rapidly and usually involve skin, eye or respiratory irritation; and
- H-E/H (unknown or no effects): If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future.

In Aggregate IDS, queried from January 1, 1999, to December 31, 2009, there are 1218 incident involving rodenticides (1126 HDs and 92 HEs)[4]. Because it falls within the categories reported as counts (which includes minor, unknown or no effects), there is no unique report that provides details about the incident and single chemical incidents are not distinguished from multiple

[4] There were no incidents reported for the active ingredient warfarin sodium salt in Aggregate IDS. Note: there was only one warfarin sodium salt product registered during the period of 1995-2009.

chemical incidents; however, a high frequency of incidents indicates there is a high potential for exposure and vice versa.

For the Main IDS, queried from January 1, 1999 to December 31, 2009, there are 321 cases reported that involve the rodenticide active ingredients listed above. Of these 321 cases, there are 304 cases reported that involve exposure to a single rodenticide chemical in the database. There were no incidents reported for the new active ingredient difenacoum. These incidents were mostly (267 incidents) categorized as HCs (Human Moderates); however, there are six incidents categorized as HA (deaths) and 22 incidents categorized as HBs (Human Majors), five incidents categorized as HD (minor) and five incidents categorized as HE/H (unknown or no effects) (Figure 4). The HAs and HBs appear to be occurring to adults mostly due to ingestion, either because of suicide attempts (13 incidents or 46%) or suspected malicious intent (i.e., intentional poisonings) (6 incidents or 21%). Other deaths (HAs) and majors (HBs) are due do unintentionally ingestions (1 incident), unknown suspected exposures (2 incidents), applicator exposure (3 incidents), post application exposure to tracking powder (2 incident), and intentional ingestion (1 incident).

Figure 4: Main IDS Incidents for Rodenticides over Time by Severity

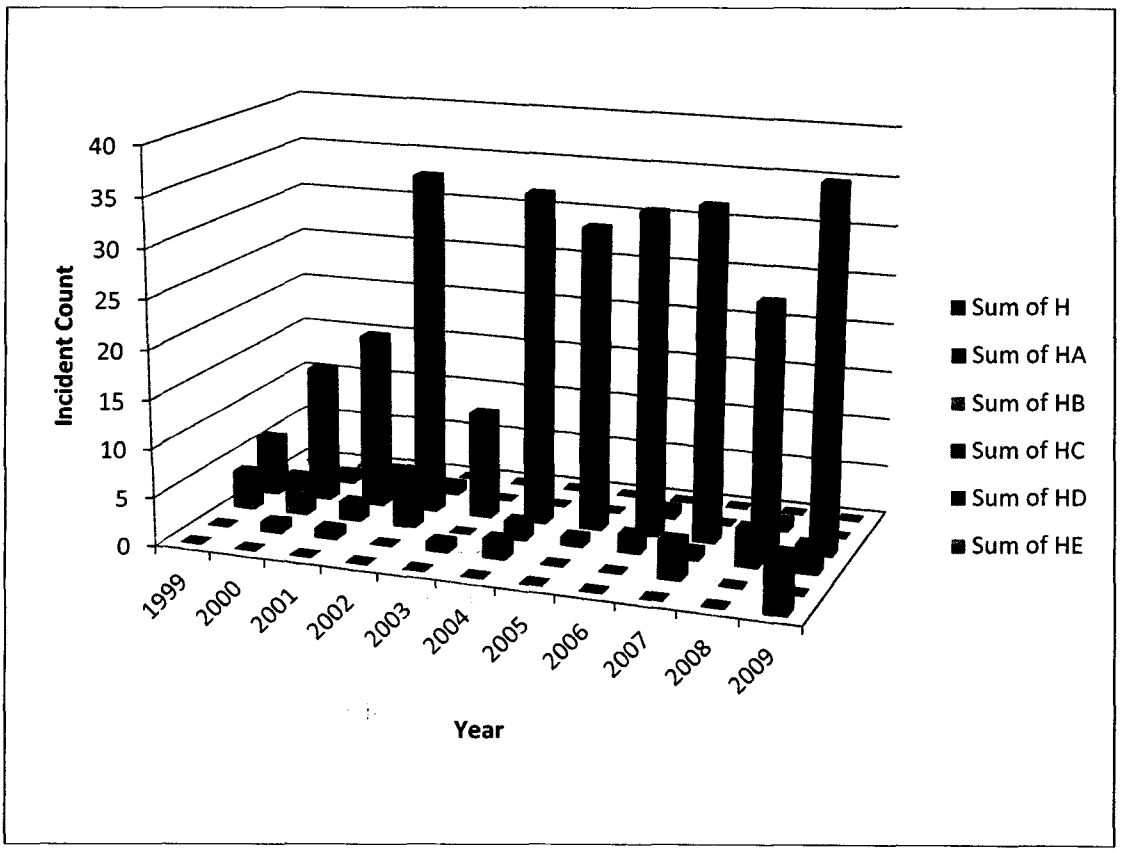
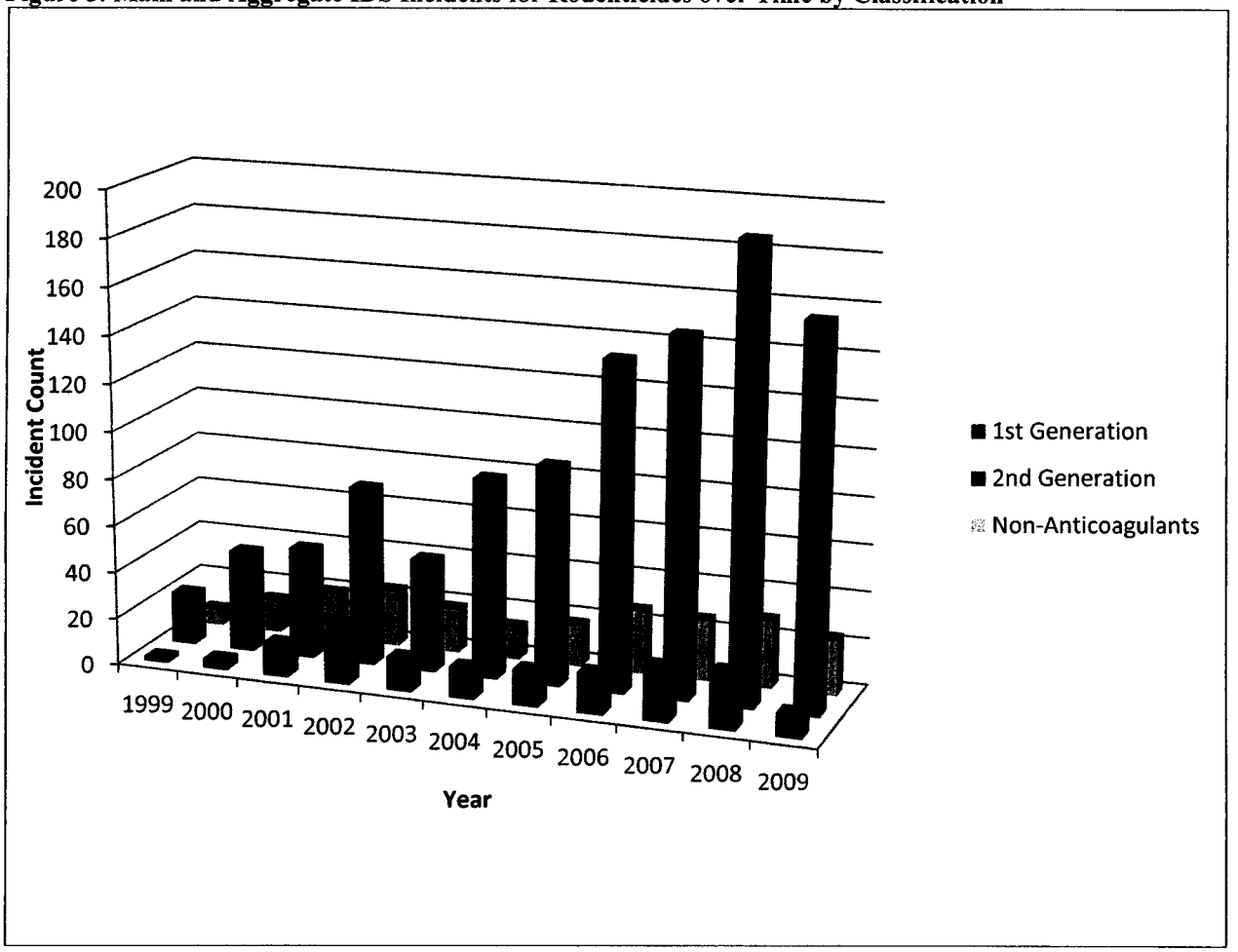


Figure 5 shows the incident counts for both Main and Aggregate IDS reported for the commensal rodenticides by classification (i.e., non-anticoagulant, 1st generation anticoagulant, or 2nd generation anticoagulant) from 1999 to 2009. Over that 11 year period, non-anticoagulant and

1st generation anticoagulant rodenticide incidents appear to be steady over time, while 2nd generation anticoagulant rodenticide incidents appear to have been increasing coming to a peak in 2008, and decreasing in 2009.

Figure 5: Main and Aggregate IDS Incidents for Rodenticides over Time by Classification



Of the rodenticide active ingredients queried in Main and Aggregate IDS, brodifacoum accounts for the most incidents (41%), followed by bromadiolone and bromethalin which account for 22% and 12%, respectively (Table 4). The deaths (HAs) and majors (HBs) appear to be occurring to adults mostly due to ingestion, either because of suicide attempts (15 incidents or 52%) or suspected malicious intent (6 incidents or 21%).

Table 4: Rodenticides Ranked by Total Exposure Count from Main and Aggregate IDS

Rodenticide	% of incidents in IDS	# of incidents in IDS	# of HAs (Deaths) and HBs (Majors)
Brodifacoum	41%	434	2 HAs (both malicious intent), 15 HBs (10 were suicide attempts and 1 malicious intent)
Bromadiolone	22%	230	-
Bromethalin	12%	129	3 HBs (1 case malicious intent, 1 case suicide attempt)
Diphacinone	12%	124	2 HAs (1 malicious intent)
Zinc phosphide	6%	65	1 HA, 3HBs (2 cases were suicide attempts)
Warfarin	3%	28	1 HA (suicide), 1 HB (malicious intent)
Difethialone	2%	25	-
Diphacinone, sodium salt	1%	10	-
cholecalciferol	1%	10	-
chlorophacinone	0.3%	3	-
Warfarin, sodium salt	0.1%	1	1 HB (suicide attempt)
Difenacoum	0.1%	1	-

- has no HA (deaths) or HBs (majors) associated with this chemical in IDS.

Of the rodenticide active ingredients queried in Main and Aggregate IDS, the products associated with the most incidents were D-CON MOUSE PRUFE II (Reg. No. 003282-00065) (320 incidents or 20%), followed by D-CON READY MIXED GENERATION II (Reg. No 003282-00081) (116 incidents or 7%), and CONTRAC ALL-WEATHER BLOX (Reg. No. 012455-00079-003240) (98 incidents or 6%). The deaths (HAs) and majors (HBs) appear to be occurring to adults mostly due to ingestion, either due to suicide attempts (13 incidents or 46%) or suspected malicious intent (i.e., intentional poisonings) (6 incidents or 21%) (Table 5).

Table 5: Rodenticide Products Ranked by Total Exposure Count from Main and Aggregate IDS

Registration Number	Product Name	Active Ingredient	Rodenticide Type	Sum of Exposure Count	# of HAs (Deaths) and HBs (Majors)
003282-00065*	D-CON MOUSE PRUFE II	Brodifacoum	2nd Generation	320	1 HA (malicious intent), and 6 HBs (5 cases suicide attempts)
003282-00081*	D-CON READY MIXED GENERATION II	Brodifacoum	2nd Generation	116	1HB (malicious intent)
012455-00079-003240	CONTRAC ALL-WEATHER BLOX	Bromadiolone	2nd Generation	98	-
000270-00373	BROMADIOLONE BAIT BAR	Bromadiolone	2nd Generation	71	-

Registration Number	Product Name	Active Ingredient	Rodenticide Type	Sum of Exposure Count	# of HAs (Deaths) and HBs (Majors)
012455-00069-003240	CONTRAC RODENTICIDE	Bromadiolone	2nd Generation	60	-
003282-00066*	D-CON PELLETS GENERATION II	Brodifacoum	2nd Generation	56	1 HB (suicide attempt)
003282-00074*	D-CON BAIT PELLETS II	Brodifacoum	2nd Generation	55	1 HB (suicide attempt)
012455-00086-003240	CONTRAC RODENTICIDE PLACE PAC	Bromadiolone	2nd Generation	49	-
067517-00066-000478	ASSAULT ALL WEATHER BAIT	Bromethalin	Non-Anticoagulant	46	-
000270-00372	BROMADIOLONE BAIT PELLETS	Bromadiolone	2nd Generation	35	-
008845-00127*	HOT SHOT SUDDEN DEATH BRAND MOUSE AND RAT KILLER	Bromethalin	Non-Anticoagulant	34	1 HB
061282-00046	RAMIK GREEN	Diphacinone	1st Generation	29	1 HA (malicious intent)
000100-01056	HAVOC RODENTICIDE BAIT PACK PELLETS WITH BITREX	Brodifacoum	2nd Generation	22	-
008845-00125*	HOT SHOT SUDDEN DEATH BRAND MOUSE KILLER	Bromethalin	Non-Anticoagulant	22	-
012455-00016	ZP TRACKING POWDER	Zinc phosphide	Non-Anticoagulant	22	1 HB
067517-00071-000478	ASSAULT MOUSE/RAT PELLETS	Bromethalin	Non-Anticoagulant	17	1 HB (malicious intent)
012455-00076	CONTRAC RODENTICIDE READY TO USE PLACE PAC	Bromadiolone	2nd Generation	16	-
012455-00075	CONTRAC RAT AND MOUSE BAIT READY TO USE PLACE PACS	Bromadiolone	2nd Generation	15	-

Registration Number	Product Name	Active Ingredient	Rodenticide Type	Sum of Exposure Count	# of HAs (Deaths) and HBs (Majors)
012455-00056	DITRAC TRACKING POWDER	Diphacinone	1st Generation	14	1 HA (suspected exposure to product)
003282-00009*	D-CON MOUSE PRUFE KILLS MICE	Warfarin	1st Generation	13	-
012455-00079	CONTRAC ALL-WEATHER BLOX	Bromadiolone	2nd Generation	11	-
012455-00018-003240	ZP POCKET GOPHER BAIT	Zinc phosphide	Non-Anticoagulant	11	-
000100-01056-061282	HAVOC RODENTICIDE BAIT PACK PELLETS WITH BITREX	Brodifacoum	2nd Generation	10	-
061282-00023	RAMIK GREEN MINI BAIT PACKS	Diphacinone	1st Generation	10	-

- has no HA (deaths) or HBs (majors) associated with it in IDS.
*products that are on the cancellation list

3. National Pesticide Information Center (NPIC)

NPIC is a cooperative effort between Oregon State University and EPA which is funded by EPA to serve as a source of objective, science-based pesticide information and respond to inquiries from the public and to incidents. NPIC functions nationally during weekday business hours through a toll-free telephone number in addition to the internet (www.npic.orst.edu) and email. Similar to Poison Control Centers, NPIC's primary purpose is not to collect incident data, but rather to provide information to inquirers on a wide range of pesticide topics, and direct callers for pesticide incident investigation and emergency treatment. NPIC receives approximately 25,000 calls per year, with about 4000 of these being incidents. NPIC collects the information about the incidents and records that information in a database. NPIC is a source of national incident information, but generally receives fewer reports than IDS. Regardless, NPIC can provide an additional source of incident information.

Unlike IDS, incidents reported to NPIC are assigned a certainty classification, which helps ascertain whether the exposure and reported outcome are related. However, NPIC has only recently begun recording a severity classification (i.e., whether the outcome was severe or minor). Of all the rodenticide human incidents, only 27 included severity classifications ("minor," "moderate," and "asymptomatic") and therefore the rodenticides are not sorted according to fatality count or hazard factor as done for IDS. Table 6 depicts the breakdown of reported rodenticide human incidents by Certainty Index classification for the time period 1999-2010. Although a majority of the incidents were considered "unclassifiable," they were

considered in this review. This is consistent with the review of IDS incidents, which are not classified according to their certainty.

Table 6: NPIC – Rodenticide Human Exposures Incidents, by Certainty Index

Certainty Index	Exposure Count
Probable	1
Possible	9
Unlikely	31
Unclassifiable	165

For NPIC from 2005 to 2010, there were 1527 total calls regarding rodenticides received by NPIC in the database. Of these total calls, 204 were incidents, 2 were suspected incidents and 1321 (or 87%) were information calls. Of the rodenticides queried in the NPIC database, zinc phosphide accounts for the most calls, 50%, and most incidents, 39% (Table 7). There were no calls in the NPIC database regarding diphacinone sodium salt or warfarin sodium salt. The Agency examined the calls to NPIC regarding rodenticides and found that they have declined from 2005 to 2010 by about 60% (Table 8). The rodenticide related incidents reported to NPIC were due primarily to misuse that included, but were not limited to, the following scenarios: child accidental contact; child ingestion or suspected ingestion; adult accidental ingestion; adult contact; malicious intent; suicide attempts; and inquiries about the safety of eating food from a garden after a rodenticide had been used in or near the garden.[5]

Table 7: Rodenticides Ranked by Calls to NPIC from 2005-2010

Rodenticide	Incident	Suspected Incident	Information	Grand Total	% of calls to PCC
ZINC PHOSPHIDE	80	1	689	770	50
BROMADIOLONE	27	-	223	250	16
DIPHACINONE	21	1	124	146	10
BROMETHALIN	14	-	100	114	7
CHLOROPHACINONE	21	-	50	71	5
WARFARIN	28	-	35	63	4
BRODIFACOUM	9	-	52	61	4
DIFETHIALONE	4	-	40	44	3
CHOLECALCIFEROL	-	-	6	6	0.4
DIFENACOUM	-	-	2	2	0.1

[5] The inquiries regarding safety of eating food from a garden after a rodenticide had been used in or near the garden were classified by NPIC as incidents; however, the narrative suggests that these may also be interpreted as informational calls. Use in this manner is a misuse.

Table 8: Rodenticide Calls to NPIC by Year from 2005 to 2010

Year	Incident	Suspected Incident	Information	Grand Total
2005	38	1	318	357
2006	55	-	306	361
2007	31	-	246	277
2008	41	1	191	233
2009	-	-	153	153
2010	39	-	107	146
Grand Total	204	2	1321	1527

4. NIOSH Sentinel Event Notification System for Occupational Risks (SENSOR)

The NIOSH SENSOR database covers 12 states from 1998-2006, although reporting varies from state to state. Pesticide-related incidents are collected from Department of Labor workers' compensation claims when reported by physicians, reports from State Departments of Agriculture, from poison control centers and from State Departments of Health based on reports by physicians suspecting pesticide exposure, so each call in the SENSOR database is likely to correspond to an exposure incident. Although both occupational and non-occupational incidents are included in the database, the data in SENSOR are predominately occupational incidents, and is of particular value in providing that information. A state SENSOR contact specialist performs follow-up with workers and obtains medical records to verify symptoms, circumstances surrounding the exposure, severity, and outcome. Using standardized protocol and case definitions, SENSOR coordinators at State Departments of Health enter the incident interview description provided by the medical report, physician and patient into the SENSOR data system, accessible to participating states and EPA. In-depth investigations for case confirmation are performed giving the Agency high confidence in the information provided. The ability to detect trends over time for SENSOR data is limited due to a generally small number of incidents and varying degrees with which the states track incidents.
http://www.cdc.gov/niosh/topics/pesticides/overview.html

There were 50 rodenticide incidents reported to NIOSH SENSOR from 1998-2006. Of these, there was one death (no details available), two were classified high severity, 12 were classified as moderate severity and 28 were classified as low severity and there were 7 with unknown severity. Of these 50 incidents, 17 incidents included narratives containing details about those incidents. Six incidents were unintentional occupational exposures in the workplace, six incidents were suicide attempts by adults, two incidents were accidental ingestion by children and three incidents were suspected ingestions by children found near rodenticide baits. Of the rodenticides queried in the SENSOR database, brodifacoum accounts for the most incidents, 28% (Table 9).

Table 9: Rodenticide Ranked Calls to SENSOR from 1998-2006

Rodenticide	% of calls to SENSOR	# of calls to SENSOR
Brodifacoum	28%	14
Warfarin	26%	13
Chlorphacinone	16%	8
Zinc Phosphide	12%	6
Diphacinone, Sodium Salt	8%	4
Bromadiolone	6%	3
Diphacinone	2%	1
Warfarin, Sodium Salt	2%	1

5. California Pesticide Illness Surveillance Program (PISP) Incident Data

The Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries. Case reports are received from physicians and via workers' compensation records. The local County Agricultural Commissioner investigates circumstances of exposure. Medical records and investigative findings are then evaluated by DPR technical experts and entered into an illness registry.

PISP contains both residential and occupational pesticide incidents. PISP has limited coverage (only California) and is not particularly useful for trend over time information. However, the incident information is entered by professionals with expertise in pesticides, with extensive follow-up on each reported case so there is a high level of confidence in the information provided for each reported incident. http://www.cdpr.ca.gov/docs/whs/pisp.htm

Sixteen incidents that are attributable to rodenticide exposures were reported to the California Pesticide Illness Surveillance Program between 2004 and 2008. These exposures included three accidental exposures to adults (through contact while applying), three exposures to children ingesting products used in home by parents, one exposure was due to an outdoor product being used indoors, and nine suicide attempts.

IV. LITERATURE REVIEW

The available literature agrees that accidental ingestion of anticoagulant rodenticides is occurring to children. Many of these sources agree that these child exposures can be managed with home observation. Caravati et al. (2007) developed a guideline to assist poison control center personnel in the out-of-hospital triage and initial management of patient with suspected exposure to SGARs. They analyzed AAPCC data from 2000 to 2003, and found that 0.7% of unintentional ingestions of SGARs, for all reported ages, were classified as having moderate or major effects or death. They recommend that patients with unintentional ingestion of less than 1 mg of SGAR active ingredient (which includes practically all unintentional ingestions in children less than 6 years of age) can be safely observed at home without laboratory monitoring. However, they also recommend that symptomatic patients (i.e. experiencing bruising or bleeding) with unintentional ingestion of SGAR should "refer to the emergency department immediately." Mullins et al. (2000) conducted a retrospective review of poison center charts involving pediatric SGAR exposures occurring in two 2-year periods. They found that although some children had slightly elevated prothrombin times, none required or received vitamin K or

experienced any bleeding. They, similarly, concluded that normal preschool-aged children with unintentional acute exposures to SGAR rodenticides do not require any routine follow-up laboratory studies and do not require medical intervention. Bartlett (2003) also concluded, in his review of nondrug substances that cause harm, that the vast majority of rodenticides in use at that time were anticoagulant products and, unless large amounts are ingested, these rodenticides have shown to be relatively harmless. Shepherd et al. (2002) characterized the toxicity from single, acute brodifacoum ingestions in young children and evaluated the utility of gastrointestinal decontamination in preventing toxicity. They found that acute pediatric ingestions of brodifacoum rarely caused clinical effects and were not associated with life-threatening symptoms or death in young children. They conclude that "it seems reasonable that acute unintentional ingestion of small quantities of brodifacoum by young children can be adequately managed with home observation and parent education."

Kendrick (2006) found that studies with in the last five years show that most unintentional SGAR ingestions can be managed at home with close outpatient follow-up, but concludes that the placement of rodenticide baits make accidental ingestion by children a realistic concern.

Badakhs et al (2010) analyzed data from the Louisiana Hospital Inpatient Discharge Database from 1998 through 2007 to characterize hospitalizations involving pesticides. They found that while only six percent of the cases in the final dataset of pesticide-related hospitalizations were due to rodenticides, children had a significantly higher rate of rodenticide exposure than adults (i.e., 14% of the pesticide-related children hospitalizations involved rodenticide exposure vs. 2% of the pesticide-related adult hospitalizations involved rodenticide exposure). The majority of the rodenticide hospitalizations (64%) occurred to very young children (ages 0 to 4 years old). They conclude that rodenticide pellets being placed in areas accessible to children coupled with the hand-to-mouth behavior of young children and their accidental contact with household pesticides are reflected in the elevated children's exposure rates. Further, the trend observed among young children reinforces the importance of protecting children from exposures to potentially hazardous products such as rodenticides.

V. DISCUSSION AND CONCLUSION

When looking across human incident data sources, as well as the open literature, rodenticides are found to be involved in numerous incidents, especially involving children less than 6 years old. These exposures to children are especially evident in the analysis of the AAPCC data which showed an average of 15,000 exposures per year occur to children under 6 years old from 1999 to 2009. While exposures generally result in no clinical harm to children, the resulting human exposures to rodenticides have the potential to result in severe outcomes and/or medical care.

According to AAPCC data from 1999-2005, even though only 1% of the children less than 6 years old were symptomatic as a result of rodenticide exposure, 25% sought treatment in a health care facility. The Agency believes that the number of non-symptomatic exposure incidents is unacceptably high because of the social costs associated with evaluating and treating children who might have been exposed.

Almost all incidents occurring due to rodenticide exposure are the result of label directions, to keep bait away from children, pets and non-target wildlife, not being followed. Despite label

directions stating "apply bait out of the reach of children," exposures to children are happening, even in cases where users are attempting to comply. This may be due to the size, shape and placement of rodenticide baits, such that they are easily accessed and handled by children, in combination with the hand-to-mouth behaviors of small children. Additionally, review of available exposure information from IDS, NPIC, NIOSH SENSOR, and CA PISP, suggests that children appear to gain access to baits placed in homes because 1) parents underestimate places their children are capable of accessing and 2) children visit a different environment (such as grandparents, friends, neighbor's) and their parent or guardian is unaware that the baits are accessible.

Subsequently, it follows that the RMD proposal (containing rodenticides in bait stations that are tamper-resistant) may mitigate child incidents involving rodenticides.

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Appendix A

Table A1: Incident Data System (IDS) Summary of Human Deaths (HAs) and Human Majors (HBs) from 1999-2010

Incident Package Report	Incident Date	Location	Reg. Number	Product Name	PC Code	Ingredient Name	Exposure Type	Incident Description
008626 - 00003	3/18/1999	BICENTENNIAL, CA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HB	A 25 year old female attempts suicide
008701 - 00001	4/13/1999	ATLANTA, GA	012455-00016	ZP TRACKING POWDER (4 OZ., 1.1 & 25 LB.)	088601	Zinc phosphide	HB	A 76 year old male had exposure to tracking powder. He used the product on the property where he works on cars over the period of about six months. Patient presents now with abdominal pain with negative Japroscopy findings, increased prothrombin time, decreased fibrinogen, elevated BUN, decreased platelets. metabolic acidosis, increased temp. He has a history of bladder cancer, pulmonary embolism and diverticulitis
009738 - 00001	12/1/1999	LINCHBURG, TN		HAVOC RODENTICIDE BAIT PACK	112701	Brodifacoum	HB	A 67 year old male became ill with edema and renal failure. He ate meat that was suspected to have the product on it.
010103 - 00001	4/12/2000	CONYERS, GA		ZINC PHOSPHIDE DUST	088601	Zinc phosphide	HA	A male in his 70s applied 10 lbs of the product in a car storage area. He did not wear PPE. He experienced fever/hyperthermia, tremors, renal failure, diaphoresis, and eventually death.
010768 - 00006	6/6/2000			JUST ONE BITE RAT POISON BAR	112001	Bromadiolone	HB	A 32 year old female had dermal exposure to product. She experienced blood clots in urine, fatigue and low abdominal pain. She was treated with multiple transfusions and vitamin K.
010849 - 00004	10/29/2000	EVERETT, MA		BRODIFACOUM	112701	Brodifacoum	HB	An 87 year old female suspected "self poisoning" attempt.

Incident Package Report	Incident Date	Location	Reg. Number	Product Name	PC Code	Ingredient Name	Exposure Type	Incident Description
011027 - 00002	8/25/2000	CA		D-CON BAIT PELLETS (BRODIFACOUM)	112701	Brodifacoum	HB	A 23 year old male suicide attempt
011027 - 00005	10/29/2000	CA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HB	A 48 year old male suicide attempt
011390 - 00001	1/1/2001	SANFORD, FL	067517-00071-000478	REAL KILL RAT & MOUSE KILLER PELLETS	112802	Bromethalin	HB	Unknown age poisoning victim
011489 - 00001	5/16/2001	MELBOURNE, FL	012455-00056	DITRAC TRACKING POWDER (6 & 25 LB PAILS)	067701	Diphacinone	HA	Unknown age adult died from unknown causes. The product was found at the work site.
012715 - 00001	2/1/2002	AZ	000100-00987	BRODIFACOUM	112701	Brodifacoum	HB	Unknown age adult male with elevated PT and PTT levels. No other information.
013052 - 00023	1/1/2002	MA		D-CON PRODUCT UNIDENTIFIED	112701	Brodifacoum	HB	An unknown age adult female ingested the product over a couple of months. She experienced hearing loss and paresthesia.
013565 - 00008	12/18/2001	SAN FRANCISCO, CA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HB	A 20 year old female was diagnosed with rodenticide poisoning. She used the bait stations in a residence and moved them about 2 times per day with bare hands. She experienced excessive bleeding and bruising.
013565 - 00011	10/29/1999	CA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HB	A 27 year old male suicide attempt.
013792 - 00007	5/5/2002	SAN DIEGO, CA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HB	A 53 year old male suicide attempt.
013858 - 00001	3/10/2003	PADUCAH, KY		TALON G RODENTICIDE (PELLETS)	112701	Brodifacoum	HA	A 46 year old male died from cerebral hemorrhage. Suspected homicide.
014083 - 00007	4/11/2002	CA		UNKNOWN - 2% ZINC PHOSPHIDE	088601	Zinc phosphide	HB	A 33 year old female suicide attempt
014118 - 00027	9/1/2002	LOS ANGELES, CA	008845-00127-	REAL KILL RAT KILLER PLACE	112802	Bromethalin	HB	An unknown age adult female and her husband became ill 8 months after

Incident Package Report	Incident Date	Location	Reg. Number	Product Name	PC Code	Ingredient Name	Exposure Type	Incident Description
			000478	PACKS				she placed product in her heating vents.
015097 - 00001	5/21/2004	BONNERS FERRY, IA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HA	Suspected poison of a 72 year old male. He experienced dyspnea and sudden death
016043 - 00001	11/6/2004	WASHINGTON, DC	061282-00046	RAMIK GREEN	067701	Diphacinone	HA	Suspected poisoning of unknown age female. She experienced a massive heart attack and sudden death.
016036 - 00023	10/17/2004	CORCORAN, CA	062577-00007	ECHOLS MOUSE & RAT PELLETS	086002	Warfarin	HB	Suspected poisoning of unknown age female.
016136 - 00006	11/12/2004	TN	003282-00081	D-CON READY MIXED BAIT BITS 3 OZ 4 PK.	112701	Brodifacoum	HB	Suspected poisoning of 33 year old female. She experienced abdominal cramps, vomiting, diarrhea, and hydroencephalopy
017138 - 00006	12/4/2005	MADISON, WI	003282-00066	D-CON BAIT PELLETS	112701	Brodifacoum	HB	An unknown age adult male attempted suicide/poisoning
017893 - 00017	3/5/2006	CA		SUPER COUMADIN PRODUCT	086003	Coumadin sodium	HB	A 43 year old female attempted suicide
018793 - 00001	6/20/2007	TERRELL, TX		D-CON (UNSPECIFIED FORMULATION)	086002	Warfarin	HC,HA	Death of 15 yr. old male after possible exposure to D-Con; autopsy results pending. Mother has minor GI bleeding after eating beans contaminated w/product.
019260 - 00001	10/9/2007	POLLAND, IN	000100-01055-061282	HAVOC XT BLOK KILLS RATS AND MICE	112701	Brodifacoum	HB	Unknown age adult male was exposed to product at work over and unknown period of time. He experienced malaise and was recently admitted to the ER with difficulty breathing and anemia.
019519 - 00037	3/13/2008	CA		ZINC PHOSPHIDE	088601	Zinc phosphide	HB	A 25 year old female attempts suicide
020180 - 00020	5/1/2008	CA	003282-00074	D-CON RODENTICIDE PELLETS	112701	Brodifacoum	HB	A 20 year old male attempted suicide

Incident Package Report	Incident Date	Location	Reg. Number	Product Name	PC Code	Ingredient Name	Exposure Type	Incident Description
				(UNSPECIFIED)				
021605 - 00008	9/2/2009	SAN DIEGO, CA		TROUNCE (UNSPECIFIED)	112802	Bromethalin	HB	A 44 year old female attempted suicide
021982 - 00005	5/10/2010	CA	003282-00065	D-CON MOUSE PRUFE II	112701	Brodifacoum	HB	A 23 year old male suicide attempt